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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,664	06/26/2003	Takatomo Hisamatsu	018961-063	3993
7590 03/27/2006				
BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			EXAMINER POUS, NATALIE R	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,664

Applicant(s)

HISAMATSU ET AL.

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/26/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/30/05, 06/28/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract exceeds the limitation of 150 words. Appropriate correction is required.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 3, 5, 6 and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (US 5911715).

Regarding Claim 1, Berg teaches a catheter (50) comprising: a proximal shaft (62); a distal shaft (56) connected to a front portion of said proximal shaft (58); a hub provided to the rear side of said proximal shaft; a balloon provided at a front portion of said distal shaft (at 52); balloon lumen (within dilation catheter 52) for communicating said hub to the inside of said balloon; and a guide wire lumen for allowing a guide wire (53) to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture positioned on the distal side from a front end of said balloon (at 53) and a proximal side aperture positioned on the rear side from a rear end of said balloon (at proximal end of apparatus 50); wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft (56) is configured as a grooved portion having a groove (61).

Regarding Claim 2, Berg teaches a catheter according to claim 1, wherein said groove is formed into spiral shape or annular shape (fig. 10).

Regarding Claim 3, Berg teaches a catheter according to claim 2, wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55).

Regarding Claim 5, Berg teaches a catheter according to claim 1, wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55).

Regarding Claim 6, Berg teaches a catheter according to claim 1, wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is

larger than that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11c).

Regarding Claim 11, Berg teaches a catheter according to claim 1, wherein said groove is formed in an outer surface of said distal shaft (fig. 9).

5. Claims 1, 2, 7, 8, 10, 11, 12, 13, 18, 19, 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith (US 5217482).

Regarding Claim 1, Keith teaches a catheter comprising: a proximal shaft (22); a distal shaft (66, 82) connected to a front portion of said proximal shaft (22); a hub (42) provided to the rear side of said proximal shaft; a balloon (26) provided at a front portion of said distal shaft (fig. 1); balloon lumen (106) for communicating said hub (Column 5, proximate lines 55-58) to the inside of said balloon; and a guide wire lumen (52) for allowing a guide wire (50) to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the distal side from a front end of said balloon (26) and a proximal side aperture (92) positioned on the rear side from a rear end of said balloon (26); wherein at least a front portion, positioned on the rear side from said balloon, of said distal shaft (fig. 4) is configured as a grooved portion having a groove (112, 114).

Regarding Claim 12, Keith teaches a catheter comprising: a proximal shaft (22) having a high rigidity (Column 6, proximate lines 60-65), a distal shaft (66, 82) provided on a front portion of said proximal shaft so as to be in fluid communication with said proximal shaft (Fig. 2) and having a rigidity lower than that of said proximal shaft

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(Column 8, proximate lines 36-40); a hub (42) connected to the vicinity of a rear end of said proximal shaft (22) and configured to allow a pressure applying apparatus to be connected to said hub (Column 5, proximate lines 55-58); a balloon (56) provided on a front side of said distal shaft so as to be in fluid communication with said distal shaft and a guide wire lumen (52) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (94) positioned on the front side from a front end of said balloon and a proximal side aperture positioned on the rear side (92) from a rear end of said balloon; wherein at least a distal portion of said distal shaft is configured as a grooved portion having a groove (112, 114).

Regarding Claims 2 and 13, Keith teaches a catheter according to claims 1 and 12, wherein said groove is formed into spiral shape or annular shape (Column 9, proximate lines 19-33).

Regarding Claims 7, 19 Keith teaches a catheter according to claims 1 and 12, wherein said grooved portion is provided at a portion adjacent to said balloon. It is noted that fig. 4 illustrates wherein the distal shaft portion and the balloon are made of the same material, and the intermediate portion 36a, may be of any desired length.

Regarding Claims 8 and 20, Keith teaches a catheter according to claims 1 and 12, wherein said distal shaft is made from a polymer material having a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm² or more (Column 7, proximate lines 34-36). Keith teaches wherein the distal shaft is formed of a high-density polyethylene, which inherently has a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm².

Regarding Claims 10 and 22, Keith teaches a catheter according to claims 1 and 12, wherein said distal shaft has a distal portion (34) and a proximal portion (110), and the rigidity of said proximal portion (110) of said distal shaft is lower than that of said proximal shaft (22) and is higher than that of said distal portion (34) of said distal shaft (Column 9, proximate lines 1-10).

Regarding Claims 11 and 23, Keith teaches a catheter according to claim 1, wherein said groove is formed in an outer surface (114) of said distal shaft.

Regarding Claim 18, Keith teaches a catheter according to claim 12, wherein said grooved portion is positioned on the rear side from said balloon (fig. 1).

6. Claim 24 rejected under 35 U.S.C. 102(b) as being anticipated by Heimberger (US 5125919). Heimberger teaches a medical tube comprising: a tube-like shaft (2); and a lumen (3) formed in said shaft ; wherein said shaft includes a groove (6) formed with its depths changed in the direction toward a distal end of said medical tube (Column 2, proximate lines 35-45).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Berg.

Regarding Claims 14, 16 and 17, Keith teaches a catheter according to dependent claims 1 and 2, but fails to disclose wherein the pitch of said spiral or annular groove is changes over the length of the grooved portion of the distal catheter. Berg teaches a balloon catheter wherein the grooved portion may have varying width and depths in order to provide variation in flexibility from groove to groove. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Keith with varying pitch of the spiral grove in order to provide variation in flexibility along the grooved portion.

9. Claims 4, 9, 15 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Keith as a matter of design choice.

Keith teaches all of the limitations of preceding dependent claims 1 and 12 as previously disclosed, but fails to describe the following:

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- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more.

Regarding the limitations wherein the groove is in a range of 30 to 90% of the wall thickness of said distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more, Keith teaches a device wherein the grooves are in place in order to provide a smooth transition from the proximal rigid portion to the more flexible distal portion, but does not teach the exact depth of the grooves in relation the thickness of the shaft. It appears that the device of Keith performs the task of providing a smooth transition from the proximal rigid portion to the more flexible distal portion equally well as that disclosed in the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose make the depth of the groove in a range of 30 to 90% of the wall thickness of the distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

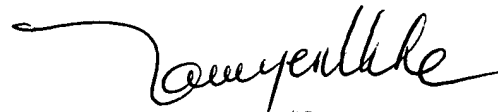
Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
3/9/06


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
3/17/06

Continuation of Attachment(s) 6). Other: IDS cont: 11/12/2003, 12/10/2003, 12/30/2004, 06/28/2004